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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,575	01/27/2000	SJEF SMEEKENS	ARNO114646	6916

7590 01/13/2004  
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/423,575

Applicant(s)

SMEEKENS ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on December 17, 2003. The request for RCE is accepted and is established with the status of the application as follows:

- a. the filling date of this RCE is established as January 27,2000;
  - b. Claims 1-4 are amended. Claims 5-17 cancelled.
2. Applicants' response to the earlier office action filed on October 14, 2003 is reconsidered and has been entered.

***Response to Arguments***

3. Applicants' response to the office action is fully considered and found persuasive.
4. With reference to the rejection under 35 USC 112 second paragraph, Applicants amendment and arguments are fully considered and the rejection is with drawn herein in view of the amendment and new grounds of rejection.
5. With reference to the rejection under 35 USC 102(e), Applicants amendment and arguments are fully considered and the rejection is with drawn herein in view of the amendment and new grounds of rejection.

***New Grounds of rejections***

***Sequence Rules***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

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Figure 1 in the instant disclosure is a nucleic acid sequence with more than 10 nucleotides, which is not identified by SEQ ID NO.

*Claim Rejections - 35 USC § 112*

*Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for modifying flowering in plants with a full length DNA sequence coding for ATH1 gene product, does not reasonably provide enablement for a method for modifying flowering in plants with partial sequence coding for an ATH1 gene product inhibiting or promoting the production of ATH1 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (*See In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include, but are not limited to:

*Quantity of Experimentation Necessary*

*Amount of Direction and Guidance*

*Presence and Absence of Working Examples*

*Nature of the Invention*

*Level of predictability and unpredictability in the art*

**Nature of the Invention:**

The invention is directed to method of modifying flowering in plants (by inhibiting / promoting ATH1 protein) with a construct comprising a complete or partial DNA sequence coding for an ATH1 gene product under the control of a functional plant promoter, wherein the gene product is encoded by the nucleotide sequence of Figure 1.

**Amount of Direction and Guidance:**

The specification demonstrates a method for modifying flowering with a construct comprising full-length sequence coding for ATH1 gene product under the control of a plant promoter (see examples 3-5 of specification) by overexpressing the with full-length the sequence coding for ATH1 gene product in plants to delay the flowering process (see the example 3 of specification) and inhibiting ATH1 gene expression in plants by antisense ATH1, thereby influencing early flowering (see the example 4 of the specification).

The specification does not teach a method for modifying flowering in plants (by inhibiting or promoting ATH1 protein) using a partial DNA sequence coding for ATH1 gene product.

**Presence and Absence of Working Examples:**

The specification has not taught or described any working examples of inhibition or promotion of flowering using partial DNA sequences coding for ATH1 gene product.

**Level of Predictability and Unpredictability in the art:**

The specification teaches the expression of full-length DNA sequence coding for ATH1

gene product in vegetative development and in inflorescence development (see page 20, lines 9-35 of specification). Specification does not teach function of full length DNA sequence coding for ATH1 gene. In addition, the specification has not identified which regions of partial DNA sequence coding for ATH1 gene product are required for modifying or inhibition or promotion of flowering in plants.

The Art (Quaedvlieg et al. Plant Cell, vol. 7: 117-129, 1995) teaches that ATH1 gene product may be involved in a signal transduction pathway downstream of COP1, however Quaedvlieg et al. does not teach the activity or function of ATH1, such that, a predictable correlation could be made with regard to what portions of the gene are responsible for the function of ATH1 gene product.

**Quantity of Experimentation Necessary:**

Therefore, based on the lack of guidance from the specification and the art, the skilled artisan would be required to perform undue experimentation to make and use the invention commensurate in scope with the claims. The artisan would be required to express every possible partial coding sequence of ATH1 gene and determine whether such would inhibit or promote flowering in plants, because, neither the specification nor the art teaches the function or demonstrate such methods with any partial coding sequences of ATH1 gene, such analysis would be replete with trial and error experimentation, the results of which are unpredictable. Such experimentation is therefore considered undue.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite nucleotide sequence of Fig. 1, which is unclear and indefinite because it is not clear what sequences from Fig. 1 being referred to these claims. Amendment to refer a SEQ ID No. would obviate the rejection.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Quaadvlieg et al. (Plant Cell, vol. 7: 117-129, 1995).

The following rejection is made based on the case law -

It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. See, e.g., Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999); Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." MEHL/Biophile Int'l Corp. v. Milgram, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999).

Quaadvlieg et al. teach a DNA sequence coding for ATH1 gene (see page 119, column 1, Fig. 1) and a process for expressing DNA sequence coding ATH1 gene product in different parts

of a plant (seeds, leaves, and flowers), wherein Quaadvlieg et al. teaches ATH1 gene expression is most abundant in flowers and the ATH1 gene expression is modified or regulated by ATH1 gene construct (see page 122, column 1, paragraphs 1-2, page 124, lines 15-17 of paragraph 2, column 2, lines 1-9).

With regard to claim1, Quaadvlieg et al. teaches a process comprising transforming plants with a construct comprising a complete DNA sequence coding for ATH1 (encoded by the nucleotide sequence of Fig.1) under the control of a functional plant promoter (see page 124, lines 15-17 of paragraph 2, column 2, lines 1-9).

With regard to claim 4, Quaadvlieg teach modifying protein levels of ATH1 gene by controlling the expression of leader sequences of ATH1 gene open reading frame indicates strict regulation of the ATH1 protein levels (see page 124, lines 15-17 of paragraph 2, column 2, lines 1-9) and Quaadvlieg et al. teach a process for (overexpression) of ATH1 gene in transformed cells inhibits the growth of green calli (see page 124, column 2, lines 1-9).

Thus the disclosure of Quaadvlieg et al. meets the limitations in the instant claims.

***Response to Arguments:***

With regard to the response to arguments (amendment filed on 7/8/2002) to the rejection made in the previous office action under 35 USC 102(b) anticipated by Quaadvlieg et al., that the prior art does not disclose each of the limitations in the instant claims, Applicants' arguments have been fully considered, however, as discussed in the above rejection, the prior art meets each of the limitations in the instant claims because Quaadvlieg et al. teach the ATH1 gene sequence as claimed in the instant amended claims, and its <sup>overexpression</sup> ~~expression~~ in transformed cells including expression in flowers, thus based on the case law cited above, under the influence of inherency,

95. 11/8/04



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the instant method claim limitations are inherent in the teachings of Quaedvlieg et al. and would result in identical effects.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004 (new tel. # 571-272-0783 effective from 1/9/04). The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
January 8, 2004

*Jehanne S. Sifton*  
*Jehanne Sifton*  
*Primary Examiner*  
*1/8/04*